DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01P–0542]

Determination That Diazepam Autoinjector Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that Diazepam Autoinjector (diazepam for injection) 5 milligrams per milliliter (mg/mL) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for diazepam for injection 5 mg/mL.

FOR FURTHER INFORMATION CONTACT: J. Kenneth Borgerding, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ‘‘listed drug,’’ which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain

approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Diazepam Autoinjector is the subject of NDA 20–124. Diazepam Autoinjector is an automatic injection drug product indicated for the management of anxiety disorders and the treatment of epileptic and other convulsive seizures. FDA approved NDA 20–124, held by the U.S. Army (Army), on December 5, 1990. The Diazepam Autoinjector is manufactured for the Army by Meridian Medical Technologies, Inc. (MMT), and has always been listed in the ''Discontinued Drug Product List'' of the Orange Book because it is not commercially available.

On November 30, 2001, MMT submitted a citizen petition (Docket No. 01P–0542/CP1) under 21 CFR 10.30 requesting that the agency determine

whether Diazepam Autoinjector was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Diazepam Autoinjector was not withdrawn from sale for reasons of safety or effectiveness. The Army has never commercially marketed Diazepam Autoinjector. In previous instances (see, e.g., 61 FR 25497, May 21, 1996 (addressing a relisting request for glyburide tablets)), FDA has concluded that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale. There is no indication that the Army's decision not to market Diazepam Autoinjector commercially is a function of safety or effectiveness concerns, and the petitioner has identified no data or other information suggesting that Diazepam Autoinjector poses a safety risk. FDA's independent evaluation of relevant information has uncovered nothing that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA has determined that, for the reasons outlined previously, Diazepam Autoinjector was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Diazepam Autoinjector (diazepam for injection) 5 mg/mL in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to Diazepam Autoinjector (diazepam for injection) 5 mg/mL may be approved by the agency.

Dated: December 19, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

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